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| 10/525,168 | 02/22/2005 | Christopher R. Yonan | 06056-0313US1 | 5885 |

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| EXAMINER |
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HANLEY, SUSAN MARIE

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| ART UNIT | PAPER NUMBER |
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1651

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05/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/525,168 | Applicant(s) YONAN ET AL. | |
| | Examiner SUSAN HANLEY | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment and remarks filed 2/1/08 are acknowledged. Claims 1-17 remain under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Rejection Based on Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 7, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 6 and 14 have been amended to recite the limitations "wherein the staining reagent of formula I is not covalently bound to the protein-binding membrane." This new limitation is held as NEW MATTER because this newly recited negative limitation is a species that was never envisaged by the specification as-filed. The exclusion of an embodiment that is not disclosed by the specification as-filed is NEW MATTER because it was not in Applicant's possession at the time of filing. The MPEP 2173.05(j) states that:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly

excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd* mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993). See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

Response to Arguments

Claim Rejections - 35 USC § 102

The rejection of claims 6, 7, 14 and 15 under 35 U.S.C. 102(a) as being clearly anticipated by Bayramoglu et al. (July, 2002) is held in abeyance. The rejection will be reinstated should Applicant cancel the New Matter added to these claims *supra*.

Claim Rejections - 35 USC § 103

Claims 1-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Alam (US 6,174,729) in view of Hopwood et al. (1973) and Miyagi et al. (1975; abstract only).

In arguing the rejection, Applicant presents a survey of procedures known in the art for protein staining and asserts that the claimed method improves upon the prior art because the dye is rapidly removed from most binding membranes, thus decreasing the interference of background

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staining by the dye. Applicant asserts that the method does not denature or alter any characteristic antigenicity or activity possessed by the protein (p. 13-14).

Applicant summarizes the Alam, Miyagi and Hopwood. Applicant provides the structure of Procion Blue M-RS disclosed by Miyagi. Following this, applicant summarizes the rejection and concludes that the Office alleges that the artisan would have combined the references, based on the allegedly known suitability of dichlorotriazine dyes. Applicant argues that there is no evidence in the cited art that would have suggested the use of a compound of formula I, including the embodiment of Reactive Brown 10. Applicant asserts that the structure of Procion Blue M-RS disclosed by Miyagi is different than that of a compound of formula I. Applicant argues that Hopwood does not teach the use of a compound of formula I, including Reactive Brown 10 for fixation.

Applicant concludes that the Office has not established a prima facie case of obviousness because there is no evidence a compound of formula I is so structurally similar to Coomassie Blue or the other dyes used by Alam. Applicant asserts that the prior art fails to provide evidence as to whether formula I is so closely related structurally to Procion [sic] Blue M-RS that it could be used in the methods of Miyagi or Hopwood. Applicant states that the Office has failed to show "adequate support in the art" to suggest a change in structure from the disclosed compounds to a compound of formula I and the ordinary artisan would not be motivated to make the necessary molecule modification to achieve the claimed invention.

In response to applicant's argument that the Applicant's invention improves upon the prior art because the dye is rapidly removed from most binding membranes, thus decreasing the interference of background staining by the dye and that the method does not denature or alter any

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characteristic antigenicity or activity possessed by the protein, these statements are assertions that are not recited in the rejected claim(s). Hence, they have no bearing in the determination of patentability at this time. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Responding to Applicant's argument that Hopwood does not disclose Reactive Brown 10, Applicant is directed to page 392. Hopwood discloses monochloro- and dichloro- triazine dyes under the "Material and methods" heading. The third entry from the bottom is Red Brown which has the symbol designation of M-4R. As was pointed out in the last Office action, Red Brown (i.e., Procion Red Brown M 4R, see the Registry print-out, is an alternative name for Reactive Brown 10. The synonyms are listed under the heading "Other Names". Thus, Hopwood does teach Reactive Brown 10 as one of several Procion-type dyes that bind protein.

Responding to Applicant's argument that the structures of Reactive Brown 10 (which is claimed), Coomassie Blue and Procion Blue M-RS used by Miyagi are too dissimilar to suggest a change in structure from the dyes used by Alam to a compound of formula I and that the ordinary artisan would not be motivated to make the necessary molecule modifications to achieve the claimed invention, the concept that ties the references together is that Alam teaches that the spotted membrane can be stained with any dye known to bind proteins to produce a visible spot (emphasis added). Alam teaches that Coomassie blue is a typical dye (col. 7, lines 43-57), but not the only dye. Hence, the only requirement to practice the method of Alam is that the dye is known to bind proteins. Therefore, close structural similarity of dyes is not the basis that the ordinary artisan would use to select a dye to practice the method of Alam. The only prerequisite is that the dye is

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able to bind proteins. Miyagi demonstrates the equivalence of several dyes (including Coomassie Blue (used by Alam) and Procion Blue M-RS) for this purpose. Responding to Applicant's argument that the Procion blue M-RS used by Miyagi has little structural resemblance to a compound of formula I, including reactive Brown 10, the name "Procion" is an art recognized term for dyes having monochloro- or dichloro- triazine dyes that are connected to a chromophore (Hopwood, top of page 392). Thus, it is the monochloro- or dichloro- triazine ring that is common to a compound of formula I, Procion Blue M-RS (taught by Miyagi) and those dyes disclosed by Hopwood on page 392.

Hence, the ordinary artisan would have known that Procion dyes, including a compound of formula I and Reactive Brown 10, are known to bind proteins which meets the only prerequisite for the method of Alam. The commonality to Procion dyes is the monochloro- or dichloro- triazine ring and that the ordinary artisan would have recognized from Hopwood that there are a finite number of such dyes that bind proteins, including Reactive Brown 10. Therefore, the ordinary artisan is not required to make molecular adjustments to Coomassie Blue in the method of Alam to arrive at the claimed invention. Rather, the ordinary artisan is only required to select a dye that is known to bind proteins. Procion dyes are a class of dyes that bind proteins and Hopwood provides a finite number of Procion dyes, including Reactive Brown 10, from which the ordinary artisan could select to practice the instant invention.

Qin et al. (US 2003/0228621) and Katchalski et al. (US 3,873,426) are cited to further demonstrate the state of the art.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651